REMARKS

Claims 71, 72, 76-82 and 84 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Akiyama et al. in view of Al-Razzak et al (U.S. Patent No. 6,010,718). Applicants disagree and in view of the following remarks request that the Examiner reconsider and withdraw the rejection of the claims.

Applicants' claims require particular components, i.e., "(i) glyceryl behenate comprising about 10-36 weight percent of the formulation; (ii) low viscosity hydroxypropyl methylcellulose comprising about 13-18 weight percent of the formulation; (iii) 500mg of a clarithromycin component, or derivative thereof . . ."

In In Re Kubin (Fed Cir 2009), the court outlined two classes of situations where "obvious to try" is erroneously equated with obviousness under § 103. In the first class:

> what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. ... In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.

In the second class of situations where "obvious to try" is erroneously equated with obviousness under §103, the court states:

> The second class of O'Farrell's impermissible "obvious to try" situations occurs where what was "obvious to try" was to explore . . . or general approach that seemed to be a promising field of experimentation,

> where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. 853 F.2d at 903.
>
> Cited in In re Kubin (Fed Cir 2009)

These classes of impermissible "obvious to try" situations are particularly applicable to Applicants' claimed invention.

Akiyama teaches broad genera of compounds and broad genera of their weight percentages, including, e.g.:

> a swelling material that swells a viscogenic agent or accelerates the swell of a viscogenic agent caused by water (page 15, lines 16-19), in an amount of about 0.5 to 50 weight % (page 15, line 25-27)
>
> any type of viscogenic agent (page 17, lines 11-15), preferably having a viscosity of 3 to 50,000cps (page 17, lines 20-22), in amounts of about 0.005 to about 99% (page 19, lines 5-7),
>
> a polyglycerol fatty acid ester in an amount of 5-98% (page 12, lines 1-2),
>
> a antimicrobial substance in an amount of 0.0005-95% (page 26, lines 13-15),
>
> an optional coating material, and
>
> surfactants.

Akiyama further teaches that the selection of polyglycerol fatty acid ester is dependent on many factors, including the ***identity of the active compound*** and viscogenic agent.

> "the proper polyglycerol fatty acid ester can be selected with reference to the particular active ingredient (e.g., anti-HP agent, etc.), viscogenic agent, swelling material (e.g., curdlan, and/or low-substituted hydroxypropylcellulose, etc.), the particular combination thereof, and the objective form of the composition"

(sentence spanning page 10-11).

Thus, Akiyama might provide a general approach that seemed to be a promising field of experimentation, but gave only general guidance as to the particular form of the claimed invention or how to achieve it. Akiyama fails to provide the necessary direction as to which of many possible choices of polyglycerol fatty acid esters is likely to be successful with particular active ingredients.

Al-Razzak Example 1 discloses a mixture of water, clarithromycin and methocel, lactose, talc and magnesium stearate. Al-Razzak does not teach or suggest the addition of any polylglycerol fatty acid ester to its formulation nor does Al-Razzak teach or suggest the effect that including a particular polylglycerol fatty acid ester would have on its disclosed formulations.

Applicants note the previously cited reference Farah, which teaches that their preparation method and the composition of the formulation could either ***enhance or inhibit*** the release of an active agent, depending on the active agent. While Al-Razzak discloses clarithromycin, Al-Razzak does not even mention polyglycerol fatty acid esters and neither Akiyama nor Al-Razzak prepares any formulations with any polyglycerol fatty acid ester and clarithromycin. Moreover, neither reference presents any analysis of formulations comprising any combination of glyceryl behenate with clarithromycin. Thus, one of skill in the art based on the combination of Akiyama and Al-Razzak and considering the general knowledge in the art could not predict whether adding any particular polyglycerol fatty acid ester to Al-Razzak's formulation would successfully enhance, inhibit or have no effect on the release of clarithromycin.

In sum, Akiyama teaches that one of the many factors that influence the selection of a polyglycerol fatty acid ester is the active ingredient, but does not suggest which of many possible choices of polyglycerol fatty acid esters available in the art is likely to be successful. Al-Razzak fails to make reference to any polyglycerol fatty acid ester and fails to teach or suggest preparing a formulation

of clarithromycin with any polyglycerol fatty acid ester. Therefore, one of skill in the art considering Akiyama and Al-Razzak in the context of the general knowledge in the art, would not be directed to a particular polyglycerol fatty acid ester for combination with clarithromycin and a low viscosity HPMC. Furthermore, one of skill in the art could not predict based on Akiyama and Al-Razzak how any composition comprising a particular polyglycerol fatty acid ester in combination with clarithromycin and low viscosity HPMC would behave. Thus, the combination of Akiyama and Al-Razzak fails to render the invention as claimed obvious.

In view of the forgoing remarks and amendments to the claims, Applicants request that the Office reconsider and withdraw the rejection of the claims under 35 U.S.C. §103 over Akiyama in view of Al-Razzak

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323, Docket No. 104101.B700017.

Respectfully submitted,

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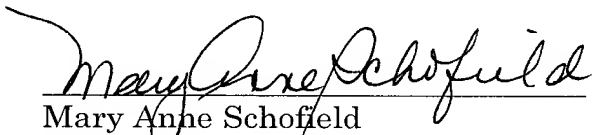

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